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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,803	07/14/2003	Linda Najdek	98.22US-CON	5789

7590 10/14/2010
Estee Lauder Companies
125 Pinelawn Road
Melville, NY 11747

EXAMINER

FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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10/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,803	Applicant(s) NAJDEK ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-24 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 14 2010 has been entered.

Receipt of Amendments/Remarks filed on April 14 2010 is acknowledged. Claim 6 was/stands cancelled. Claims 1 and 8 were amended. Claims 1-5 and 7-24 are pending. Claims 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/16/06. Therefore, claims 1-5 and 7-22 are examined on the merits herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Murray et al. (US Patent No. 4810489).

Murray et al. exemplify a lotion comprising an aqueous phase and an oil phase (a dual phase liquid cosmetic) (column 12). The aqueous phase is present in 59.05% and the oil phase is present in 38% (see manufacturing directions column 12), which reads on the instantly claimed ratio. The oil phase of the composition comprises PVP/Eicosene copolymer in 5% (see #2 of manufacturing directions, column 12). Murray teach that PVP copolymer suitable include PVP/hexadecene copolymer and PVP/eicosene copolymer. These polymers are utilized in an amount from about 1 to 10% (column 3, lines 17-34).

With regard to the functional limitation pertaining to demixing, Murray et al. discloses the same claimed demixing agent in the same amount. Note MPEP 2112.02 (11): "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding the claimed PVP copolymer, Murray et al. teach **two** different PVP copolymers, PVP/Eicosene and PVP/hexadecene. Where selection of one named species from a list of alternatives is all that is required to arrive at the instantly claimed

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subject matter, that species is anticipated. Ex Parte A., 17 USPQ 2d 1716 (Bd. Pat. App. & Inter. 1990). See also In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982). See MPEP 2131.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 7-9 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (WO 92/09266, cited on PTO Form 1449) in view of Nagy et al. (US Patent No. 5871758, cited in the Office action mailed on 12/28/07) as evidenced by Sakellariou et al. (Colloid Polym. Sci. 1995).

Applicant Claims

Applicant claims a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase, the oil phase and aqueous phase are present in a ratio from about 30:70 to about 70:30 by weight of the total composition, the composition containing a demixing-effective amount of a film forming agent wherein the composition emulsifies rapidly and uniformly upon vigorous shaking and demulsifies completely upon resting within about 5 to 20 minutes.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Davis et al. is directed to two-component pharmaceutical compositions for topical application. The composition comprises two distinct phases wherein at least one contains a drug dissolved therein. The phases each have a different liophilicity (page 2, lines 1-6). It is taught that duration of the supersaturated state is limited by evaporation taking place after the phases mix together (page 2-3, lines 34-36 and 1-2). The two phases are intended to be mixed together on or immediately prior to application (page 4, lines 1-5). It is taught that the two phases are physically and/or chemically different

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(page 4, lines 7-9). The proportion of first liquid phase to the second is from 1:1 to 1:12 (page 5-6, lines 34-35 and 1-2). It is taught that water is a necessary component of the second liquid phase (page 6, lines 17-19). The first liquid phase comprises more than one liquid that is generally more lipophilic or less-polar (column 6, lines 20-22). The compositions include anti-nucleating agents such as polyvinylpyrrolidone (example 1, 5, and 6) in an amount up to 10% by weight (page 8, lines 14-27). It is taught that the choice of anti-nucleating agent can readily be selected by simple experiment. For example preparing samples of the desired final supersaturated drug solution (i.e. mixed solution) and then adding the anti-nucleating agent allowing the samples to stand for say 2 hours and noting which solutions remain clear (page 9, lines 1-8). It is taught that the compositions of the invention are suitable for any medical, cosmetic or other treatment of the body surface (column 10, lines 14-20). The composition may comprise a variety of drugs (page 11, lines 8-17).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Davis et al. do not teach that the first liquid phase comprises an oil, although Davis et al. do teach it is generally more lipophilic or less-polar than water. However, these deficiencies are cured by Nagy et al.

Nagy et al. is directed to dual phase cosmetics. It is taught that the compositions can be utilized as a liquid dual phase makeup removal composition (claim 15) or for therapeutic purposes (column 3, lines 66-67). It is taught that these compositions provide a broad range of cleansing/conditioning potential within a single product (column 1, lines 10-12). It is taught that oil soluble actives may be unstable if in

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prolonged contact with the aqueous phase (column 1, lines 42-44). It is taught that the oil phase may be any cosmetically or pharmaceutically acceptable oil (column 3, lines 18-21). It taught that a in preferred embodiment the oil phase comprises a combination of both volatile and non-volatile oil. The amount of volatile oil used is higher than non-volatile oils. One specific combination is volatile silicone and volatile paraffin. A specific combination is cyclic silicone at 25-40% by weight, C₁₆ isoparaffin in 15-30% by weight and the non-volatile silicone at 0.1 to 1% by weight. A preferred non-volatile silicone is dimethicone. One other exemplified oils include isohexadecane. Other hydrocarbons listed as suitable include decane, dodecane, tridecane, tetradecane, etc. (column 3, lines 29-30).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Davis et al. and Nagy et al. and utilize oils in the first liquid phase. One of ordinary skill in the art would have been motivated to utilize oils as Davis et al. teach two phase compositions that can be utilized for any medical, cosmetic or other treatment of the body surface and the first phase is one that is generally more lipophilic or less-polar. Nagy et al. teach dual phase compositions that are utilized for cosmetic or pharmaceutical purposes that provide a broad range of cleansing/condition potential within a single product. Therefore, one of ordinary skill in the art would have been motivated to utilize the oils taught by Nagy et al. in the composition of Davis et al. One of ordinary skill in the art would have been motivated as both are directed to similar products with similar uses and Nagy teach that these dual phase compositions provide

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a broad range of cleansing/conditioning potential. Furthermore, one of ordinary skill in the art would have been motivated to utilize an oil depending on the active utilized. If a more oil soluble active was utilized in the composition then one of ordinary skill in the art would have been motivated to utilize an oil as taught by Nagy et al.

Regarding applicants claim that the polyvinylpyrrolidone is a demixing agent; Davis et al. do not utilize this particular verbage. However, it is taught that the choice of anti-nucleating agent, of which PVP is one choice, can readily be selected by simple experiment. For example preparing samples of the desired final supersaturated drug solution (i.e. mixed solution) and then adding the anti-nucleating agent allowing the samples to stand for say 2 hours and noting which solutions remain clear. Furthermore, as evidenced by Sakellariou, PVP is known in the art to cause phase separation (abstract, page 287, left column, second paragraph).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. in view of Nagy et al. as evidenced by Sakellariou et al. in further view of Smith (US Patent No. 5658559, cited on PTO Form 1449).

Applicant Claims

Applicant claims that the film forming agent is polyvinylpyrrolidone hexadecane copolymer.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

The teachings of Davis et al., Nagy et al, and Sakellariou et al. are set forth above. Specifically, Davis et al. teach two-component preparations. It is taught that duration of the supersaturated state is limited by evaporation taking place after the phases mix together. Nagy et al. teach dual phase compositions comprising oil. Sakellariou et al. teach that PVP is known in the art to cause phase separation.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Davis et al. do not specify that the polyvinylpyrrolidone polymer is polyvinylpyrrolidone hexadecene. However, this deficiency is cured by Smith.

Smith is directed to lotions for the treatment of a skin disease or disorder. It is taught that these compositions comprise a barrier polymer to prevent evaporation loss of moisture from the skin (column 4, lines 8-11). Useful polymers include polyvinylpyrrolidone, copolymers of vinylpyrrolidone and eicosene, copolymers of vinylpyrrolidone and hexadecane, etc. (column 4, lines 15-32).

***Finding of Prima Facie Obviousness Rational and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Davis et al., Nagy et al. and Smith and utilize copolymers of vinylpyrrolidone and hexadecane (PVP/hexadecane). One of ordinary skill in the art

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would have been motivated to utilize this polymer as Smith teaches that it prevents evaporation loss of moisture from the skin and Davis et al. teach that evaporation determines the duration of the supersaturated state. Furthermore, one of ordinary skill in the art would have been motivated to replace polyvinylpyrrolidone with copolymers of vinylpyrrolidone and hexadecane (PVP/hexadecane) as both are taught by Smith as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) the examiner misinterprets, “which samples remain clear” to mean that the phases separate but one skilled in the art would appreciate that “which samples remain clear” refers to which samples remain in the supersaturated or mixed state; that is where the drug remains supersaturated in the mixture and does not precipitate out. Applicants argue that (2) the disclosure in WO ‘266 would indicate that PVP is a stabilizing agent. Applicants’ arguments filed April 14 2010 have been fully considered but they are not persuasive.

Regarding applicants first argument, while the examiner does agree with applicants statement remain clear does not necessarily mean phase separation, the examiner disagrees with applicants that it necessarily remains in the mixed state. WO

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'266 teaches that the polyvinylpyrrolidone would be expected to help maintain the drug in solution. This does not necessarily mean that when two phases with different lipophilicities are mixed that they do not separate out.

Regarding applicants second argument, the examiner disagrees. PVP would be interpreted as helping to have the drug remain in solution and therefore not precipitate out. This does not mean that PVP would be interpreted as helping the composition to remain in a mixed state. Furthermore, the examiner cited Sakellariou to show that it is known that PVP causes phase separation. Therefore, while one of ordinary skill would reasonably expect that PVP would help aid in drug solubilization, one of ordinary skill would not necessarily expect the two phases to remain in a mixed state. Additionally, the instant specification teaches a preferred demixing agent is PVP. Since WO'266 clearly teaches the use of PVP in the claimed amount (up to 10% by weight), it would be expected to perform as a demixing agent. If it doesn't, as applicants argue the art suggests, then how do applicants get it to serve as a demixing agent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The instant claims recite a composition comprising an aqueous phase and an oil phase wherein the composition contains a film forming agent (PVP is a specific agent claimed). WO '266 specifically teaches adding PVP to one or both of the phases of the two phase compositions. Applicants have not demonstrated that the composition of WO '266 would not function as instantly claimed.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al.

Applicant Claims

The instant application claims the agent is present in an amount from about 0.01 to about 1 percent by weight of the total composition.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

The teachings of Murray et al. are set forth above. Specifically, Murray et al. exemplify a dual phase cosmetic composition comprising an oil phase and an aqueous phase wherein the oil phase comprises a PVP/Eicosene copolymer. Murray teach that PVP copolymer suitable include PVP/hexadecene copolymer and PVP/eicosene copolymer. These polymers are utilized in an amount from about 1 to 10% (column 3, lines 17-34).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Murray et al. teach that PVP/hexadecane can be utilized, Murray et al. does not exemplify a dual phase cosmetic composition comprising PVP/hexadecane.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

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Regarding the claimed amount of agent, Murray et al. teaches an amount that overlaps the instantly claimed amount (about 1% overlap). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. Furthermore, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would expect them to have the same properties. **See MPEP 2144.05 [R-5]**. Therefore, the instantly claimed amount is deemed to be *prima facie* over the range taught by Murray et al.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Nagy et al.

Applicant Claims

The instant application claims the oil phase contains a combination of volatile and non-volatile oils.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Murray et al. are set forth above. Specifically, Murray et al. exemplify a dual phase cosmetic composition comprising an oil phase and an aqueous phase wherein the oil phase comprises a PVP/Eicosene copolymer. Murray teach that PVP copolymer suitable include PVP/hexadecene copolymer and PVP/eicosene copolymer. These polymers are utilized in an amount from about 1 to 10% (column 3, lines 17-34). Oils exemplified include dimethicone in 1% (instantly claimed non-volatile oil).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Murray et al. do not teach the use of a volatile oil in addition to the non-volatile oil. However, this deficiency is cured by Nagy et al.

Nagy et al. is directed to dual phase cosmetics. It is taught that the compositions can be utilized as a liquid dual phase makeup removal composition (claim 15) or for therapeutic purposes (column 3, lines 66-67). It is taught that these compositions provide a broad range of cleansing/conditioning potential within a single product (column 1, lines 10-12). It is taught that oil soluble actives may be unstable if in prolonged contact with the aqueous phase (column 1, lines 42-44). It is taught that the oil phase may be any cosmetically or pharmaceutically acceptable oil (column 3, lines 18-21). It is taught that a preferred embodiment the oil phase comprises a combination of both volatile and non-volatile oil. The amount of volatile oil used is higher than non-volatile oils. One specific combination is volatile silicone and volatile paraffin. A specific combination is cyclic silicone at 25-40% by weight, C₁₆ isoparaffin in 15-30% by weight and the non-volatile silicone at 0.1 to 1% by weight. A preferred non-volatile silicone is dimethicone. One other exemplified oils include isohexadecane. Other hydrocarbons listed as suitable include decane, dodecane, tridecane, tetradecane, etc. (column 3, lines 29-30). It is that the oils can perform different functions in the composition and the specific choice is dependent on the purpose for which it is intended. The oils taught are those which are cosmetically acceptable (column 3, lines 19-35).

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Murray et al. and Nagy et al. and utilize volatile oils in addition to the exemplified non-volatile oil. One of ordinary skill in the art would have been motivated to manipulate the oils utilized in the cosmetic formulation as Nagy et al. teach that this is something one of ordinary skill in the art would routinely manipulate depending on the purpose of the final composition. Therefore, absent a demonstration of the criticality of the instantly claimed combination of oils, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine the optimal oils to utilize depending on the purpose of the resulting composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF
/Abigail Fisher/

Examiner, Art Unit 1616